

**STATE OF WISCONSIN
DEPARTMENT OF SAFETY AND PROFESSIONAL SERVICES**

**IN THE MATTER OF RULEMAKING :
PROCEEDINGS BEFORE THE : REPORT TO THE LEGISLATURE
DEPARTMENT OF SAFETY AND : CR 15-100
PROFESSIONAL SERVICES :**

I. THE PROPOSED RULE:

The proposed rule, including the analysis and text, is attached.

II. REFERENCE TO APPLICABLE FORMS: n/a

III. FISCAL ESTIMATE AND EIA:

The Fiscal Estimate and EIA is attached.

IV. DETAILED STATEMENT EXPLAINING THE BASIS AND PURPOSE OF THE PROPOSED RULE, INCLUDING HOW THE PROPOSED RULE ADVANCES RELEVANT STATUTORY GOALS OR PURPOSES:

Hydrocodone combination products were rescheduled to Schedule II controlled substances by the federal government effective October 6, 2014 and the Wisconsin Controlled Substances Board effective November 1, 2014. The scheduling change removed the ability for optometrists to prescribe hydrocodone combination products due to a statutory prohibition on prescribing schedule II controlled substances. 2015 Act 34 specifically added language to the statutes to allow optometrists to prescribe hydrocodone combination products pursuant to promulgation of rules.

V. SUMMARY OF PUBLIC COMMENTS AND THE BOARD'S RESPONSES, EXPLANATION OF MODIFICATIONS TO PROPOSED RULES PROMPTED BY PUBLIC COMMENTS:

The Department held a public hearing on February 4, 2016. The following people either testified at the hearing, or submitted written comments:

Peter Theo representing the Wisconsin Optometric Association
Robert Schulz representing the Wisconsin Optometry Examining Board

The Department summarizes the comments received either by hearing testimony or by written submission as follows:

The Wisconsin Optometric Association and the Wisconsin Optometry Examining Board support the proposed rules.

The Department explains modifications to its rule-making proposal prompted by public comments as follows:

The Department did not make any modifications prompted by public comments.

VI. RESPONSE TO LEGISLATIVE COUNCIL STAFF RECOMMENDATIONS:

Comment 2b: The listing of the two formulations of hydrocodone should be inserted in s. SPS 10.01 (10) (a), with the other oral analgesics, rather than in sub. (10) (am).

Response: The formulations of hydrocodone are not inserted with the oral analgesics because it addresses hydrocodone combination products regardless of how administered.

Comment 3: Based on the phrasing in s. SPS 10.01 (1) (am) (intro.), it appears to be intended that “only” the two listed formulations of hydrocodone are permitted. However, the phrasing in sub. (1) (intro.), “Therapeutic pharmaceutical agents include but are not limited to:”, is written as a list of examples, which is not an exhaustive list. To reconcile the two phrases, the department should consider amending the second sentence in sub. (10) (intro.) to state that either:

- a. “Each of the following is a therapeutic pharmaceutical agent:”.
- b. “Therapeutic pharmaceutical agents include, and, except as provided in par. [(a) 5. and 6.], are not limited to:”

Response: The Department accepts this comment in part. The Department utilizes current rule manual language and is modifying the second sentence in SPS 10.01 (10) (intro) to read:

“Except as provided in par. (am), therapeutic pharmaceutical agents include all of the following:”

All of the remaining recommendations suggested in the Clearinghouse Report have been accepted in whole.

VII. REPORT FROM THE SBRRB AND FINAL REGULATORY FLEXIBILITY ANALYSIS:

This rule does not affect small businesses.

STATE OF WISCONSIN
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IN THE MATTER OF RULE-MAKING	:	PROPOSED ORDER OF THE
PROCEEDINGS BEFORE THE	:	DEPARTMENT OF SAFETY AND
DEPARTMENT OF SAFETY AND	:	PROFESSIONAL SERVICES
PROFESSIONAL SERVICES	:	ADOPTING RULES
	:	(CLEARINGHOUSE RULE 15-100)

PROPOSED ORDER

An order of the Department of Safety and Professional Services to amend SPS 10.01 (10) (intro) and create SPS 10.01 (10) (am), relating to optometrists prescribing hydrocodone combination products.

Analysis prepared by the Department of Safety and Professional Services.

ANALYSIS

Statutes interpreted: ss. 449.18, and 961.39, Stats.

Statutory authority: s. 449.18 (6) (cm), Stats.

Explanation of agency authority:

The secretary of the department of safety and professional services shall, after consultation with the optometry examining board, the medical examining board and the pharmacy examining board, promulgate rules specifying those therapeutic pharmaceutical agents that may or may not be prescribed or administered. [s 449.18 (6) (cm), Stats.]

Related statute or rule: n/a

Plain language analysis:

Hydrocodone combination products were rescheduled to Schedule II controlled substances by the federal government effective October 6, 2014 and the Wisconsin Controlled Substances Board effective November 1, 2014. The scheduling change removed the ability for optometrists to prescribe hydrocodone combination products. 2015 Act 34 specifically added language to the statutes to allow optometrists to prescribe hydrocodone combination products pursuant to promulgation of rules.

Summary of, and comparison with, existing or proposed federal regulation: None

Comparison with rules in adjacent states:

Illinois: Illinois allows the prescribing of hydrocodone combination products by optometrist.

Iowa: Iowa allows the prescribing of hydrocodone combination products by optometrist.

Michigan: Michigan allows the prescribing of hydrocodone combination products by optometrists.

Minnesota: Minnesota allows the prescribing of hydrocodone combination products by optometrists.

Summary of factual data and analytical methodologies:

The Department consulted with the Medical Examining Board, Optometry Examining Board and Pharmacy Examining Board. The Department is promulgating rules in accordance with 2015 Act 34 provisions.

Analysis and supporting documents used to determine effect on small business or in preparation of economic impact analysis:

This rule was posted for economic comments and none were received. This rule restores the ability to optometrists to prescribe hydrocodone combination products.

Fiscal Estimate and Economic Impact Analysis:

The Fiscal Estimate and Economic Impact Analysis is attached.

Effect on small business:

These proposed rules do not have an economic impact on small businesses, as defined in s. 227.114 (1), Stats. The Department's Regulatory Review Coordinator may be contacted by email at Jeff.Weigand@wisconsin.gov, or by calling (608) 267-2435.

Agency contact person:

Sharon Henes, Administrative Rules Coordinator, Department of Safety and Professional Services, Division of Board Services, 1400 East Washington Avenue, Room 151, P.O. Box 8366, Madison, Wisconsin 53708; telephone 608-261-2377; email at Sharon.Henes@wisconsin.gov.

TEXT OF RULE

SECTION 1. SPS 10.01 (10) (intro) is amended to read:

“Therapeutic pharmaceutical agent” means a drug which is prescribed or administered for ocular therapeutic purposes. ~~Therapeutic~~ Except as provided in par. (am), therapeutic pharmaceutical agents include but are not limited to all of the following:

SECTION 2. SPS 10.01 (10) (am) is created to read:

SPS 10.01 (10) (am) Controlled substances in schedule II, limited to either of the following:

1. Not more than 300 milligrams of hydrocodone per 100 milliliters or per 100 grams or not more than 15 milligrams per dosage unit, with a four-fold or greater quantity of an isoquinoline alkaloid of opium.
2. Not more than 300 milligrams of hydrocodone per 100 milliliters or per 100 grams or not more than 15 milligrams per dosage unit, with one or more active, nonnarcotic ingredients in recognized therapeutic amounts.

SECTION 3. EFFECTIVE DATE. The rules adopted in this order shall take effect on the first day of the month following publication in the Wisconsin administrative register, pursuant to s. 227.22 (2) (intro.), Stats.

(END OF TEXT OF RULE)

This Proposed Order of the Department of Safety and Professional Services is approved for submission to the Governor and Legislature.

Dated

2/19/16

Agency


Secretary

ADMINISTRATIVE RULES

Fiscal Estimate & Economic Impact Analysis

1. Type of Estimate and Analysis

☒ Original ☐ Updated ☐ Corrected

2. Administrative Rule Chapter, Title and Number

SPS 10

3. Subject

Optometrists Prescribing Hydrocodone Combination Products

4. Fund Sources Affected

☐ GPR ☐ FED ☐ PRO ☐ PRS ☐ SEG ☐ SEG-S

5. Chapter 20, Stats. Appropriations Affected

6. Fiscal Effect of Implementing the Rule

☒ No Fiscal Effect ☐ Increase Existing Revenues ☐ Increase Costs
☐ Indeterminate ☐ Decrease Existing Revenues ☐ Could Absorb Within Agency's Budget
☐ Decrease Cost

7. The Rule Will Impact the Following (Check All That Apply)

☐ State's Economy ☐ Specific Businesses/Sectors
☐ Local Government Units ☐ Public Utility Rate Payers
☐ Small Businesses (if checked, complete Attachment A)

8. Would Implementation and Compliance Costs Be Greater Than \$20 million?

☐ Yes ☐ No

9. Policy Problem Addressed by the Rule

This rule will implement 2015 Wisconsin Act 34. Hydrocodone combination products were rescheduled to Schedule II controlled substances by the federal government effective October 6, 2014 and the Wisconsin Controlled Substances Board effective November 1, 2014. The scheduling change removed the ability for optometrists to prescribe hydrocodone combination products (due to a prohibition on prescribing schedule II). 2015 Act 34 specifically allows optometrists to prescribe hydrocodone combination products pursuant to promulgation of rules.

10. Summary of the businesses, business sectors, associations representing business, local governmental units, and individuals that may be affected by the proposed rule that were contacted for comments.

This rule was posted for economic comments for 14 days and none were received.

11. Identify the local governmental units that participated in the development of this EIA.

None. This rule does not impact local governmental units.

12. Summary of Rule's Economic and Fiscal Impact on Specific Businesses, Business Sectors, Public Utility Rate Payers, Local Governmental Units and the State's Economy as a Whole (Include Implementation and Compliance Costs Expected to be Incurred)

There is no economic and fiscal impact on specific businesses, business sectors, public utility rate payers, local governmental units or the State's economy as a whole.

13. Benefits of Implementing the Rule and Alternative(s) to Implementing the Rule

The benefit is implementation of 2015 Act 34 to allow optometrists to prescribe hydrocodone combination products.

14. Long Range Implications of Implementing the Rule

The long range implication is optometrists will be able to resume prescribing a substance they were able to prescribe prior to the rescheduling in fall of 2014.

15. Compare With Approaches Being Used by Federal Government

None.

16. Compare With Approaches Being Used by Neighboring States (Illinois, Iowa, Michigan and Minnesota)

Our surrounding states allow the prescribing of hydrocodone combination products by optometrists.

ADMINISTRATIVE RULES
Fiscal Estimate & Economic Impact Analysis

17. Contact Name

Sharon Henes

18. Contact Phone Number

(608) 261-2377

This document can be made available in alternate formats to individuals with disabilities upon request.

ADMINISTRATIVE RULES
Fiscal Estimate & Economic Impact Analysis

ATTACHMENT A

1. Summary of Rule's Economic and Fiscal Impact on Small Businesses (Separately for each Small Business Sector, Include Implementation and Compliance Costs Expected to be Incurred)

2. Summary of the data sources used to measure the Rule's impact on Small Businesses

3. Did the agency consider the following methods to reduce the impact of the Rule on Small Businesses?

- ☐ Less Stringent Compliance or Reporting Requirements
 - ☐ Less Stringent Schedules or Deadlines for Compliance or Reporting
 - ☐ Consolidation or Simplification of Reporting Requirements
 - ☐ Establishment of performance standards in lieu of Design or Operational Standards
 - ☐ Exemption of Small Businesses from some or all requirements
 - ☐ Other, describe:
-

4. Describe the methods incorporated into the Rule that will reduce its impact on Small Businesses

5. Describe the Rule's Enforcement Provisions

6. Did the Agency prepare a Cost Benefit Analysis (if Yes, attach to form)

☐ Yes ☐ No
